UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Addendum to the Risk Assessment and Science Support Branch: Final Draft of Human Health Science Chapter For 1,4-Bis(bromoacetoxy)-2-butene RED, PC Code 0360, Case 818798, Barcode D271450.

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Attached please find the following documents for the final draft human health science chapter for 1,4 Bis(bromoacetoxy)-2-butene:

1. Amended draft bibliography chapter
2. Revised draft science chapter

The purpose of this addendum is to respond to the FDA review of the first EPA draft of this science chapter. The EPA revisions address the concerns that FDA raised in their review. These are:

C FDA Comment: The FDA commented concerning the possible use of this chemical as a coating to manufactured paper--in addition to the slimicide use of the chemical introduced into the wet end of the paper-making process.

EPA response: EPA did not consider the labeled use for paper to include a coating use because of the manner in which the use pattern is stated on the label. However, the EPA suggests that the label be revised to clarify the use pattern.

- FDA Comment: The FDA uses an FDA model to calculate expected residues in the BBAB-treated paper and in the food contacting the treated paper. This results in a finding of very low residues in food that contacts treated paper. Therefore, FDA questions EPA's use of a more conservative model.

  EPA Response: The EPA did not use the FDA model to calculate residues in the BBAB-treated paper. This is because BBAB has a very low solubility in water and because of an available migration study for BBAB in treated paper which showed migration of BBAB from treated paper into food-simulating solvents. This migration study does not follow current FDA guidance for conducting a migration study. Additionally, that migration study was repeated in part to show no detectable residues in food-simulating solvents. Because the previous migration study contained contradictory results and because BBAB has limited water solubility, EPA performed a very conservative calculation for BBAB residues in food. Thus, the EPA calculations produce a BBAB dietary intake that is several orders of magnitude higher than the FDA model. EPA believes these calculations are more appropriate for BBAB than FDA's estimates.